"DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARING SCREENING OF HIGH RISK NEWBORN"

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MADRAS MEDICAL COLLEGE

CHENNAI

CERTIFICATE

This is to certify that the dissertation entitled "**A STUDY ON DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARING SCREENING OF HIGH RISK NEWBORN**" is a bonafide work done by **DR.KARTHIK.R** at Madras Medical College, Chennai in partial fulfillment of the university rules and regulations for award of **M.D., Degree in Paediatrics** (BRANCH VII) during the academic year 2013- 2016.

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I, Dr. KARTHIK.R, solemnly declare that this dissertation entitled "**A STUDY ON DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARING SCREENING OF HIGH RISK NEWBORN**" was done by me at Madras Medical College and Institute of Child Health and Hospital for Children, during 2013-2016 under the guidance and supervision of DR.REMA CHANDRAMOHAN MD., DCH., This dissertation is submitted to The Tamilnadu Dr.M.G.R Medical University towards the partial fulfillment of requirements for the award of M.D Degree in Paediatrics (Branch – VII).

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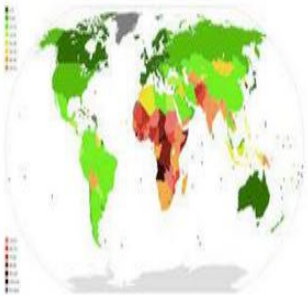
INTRODUCTION

Early detection of hearing impairment is crucial for normal social and emotional development[1]. Prevalence of deafness estimated by various studies in newborn is 1.6 per 1000. Prevalence of hearing impairment identified by neonatal hearing screening programmes across the world were: 1.6/1000 of at-risk infants (India, bilateral) approximately 1/1000 (Brazil,); 1-3/1000 (China,) 1.6/1000 (Germany, bilateral) and 0.7/1000 (Germany, unilateral); 1.05/1000 (United States, Colorado, bilateral) and 0.45/1000 (USA, Colorado, state unilateral); 1.83/1000 (United States, State of Washington); and 3/1000 in (Philippines).[2]

When hearing loss is defined as loss of > 25 dB, the prevalence of Permanent Congenital Hearing Loss (PCHL) reaches 3 babies per 1000[3].



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INTRODUCTION

CONTENTS

ABSTRACT

DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARING SCREENING OF HIGH RISK NEWBORN

BACKGROUND AND OBJECTIVES :

Early detection of hearing impairment is crucial for normal social and emotional development . Prevalence of deafness estimated by various studies in newborn is 1.6 per 1000. Objective of the study is to compare the diagnostic ability of Oto-acoustic Emission and brainstem evoked response audiometry in hearing screening of high risk infants.To determine the ideal hearing screening tool in high risk newborn and the referral rate of OAE and BERA in populations with the following risk factors- prematurity , low birth weight, neonatal jaundice and birth asphyxia.

MATERIALS AND METHODS:

The Study was designed as a cross-sectional study . A total of 144 high risk neonates admitted in newborn departments of Institute of Child Health and Institute of Obstetrics and Gynaecology during the period March 2015 to September 2015 were studied. High risk status was defined by JointCommittee of Infant Hearing criteria (JCIH 2007).

RESULT :

26 Cases were referred by OAE. 6 cases were identified with hearing loss by BERA done at 90dB and 40 dB. Referral rate was 18.1% with OAE and 4.2% with BERA. Sensitivity of OAE as 16.7 % and the specificity was 81.9 %. Positive likelihood ratio with OAE was .923. One case with sepsis had hearing loss identified with OAE but it passed BERA in both ears.One case with history of ototoxic drug administration had the result REFER with OAE. But it passed BERA in both ears.

CONCLUSION:

OAE had higher referral rate and higher number of false positives. BERA is therefore considered gold standard in hearing screening.Mean duration of NICU stay had a positive correlation with hearing loss.

INTRODUCTION

Early detection of hearing impairment is crucial for normal social and emotional development[1]. Prevalence of deafness estimated by various studies in newborn is 1.6 per 1000. Prevalence of hearing impairment identified by neonatal hearing screening programmes across the world were: 1.6/1000 of at-risk infants (India, bilateral) approximately 1/1000 (Brazil,); 1–3/1000 (China,) 1.6/1000 (Germany, bilateral) and 0.7/1000 (Germany, unilateral); 1.05/1000 (United States, Colorado, bilateral) and 0.45/1000 (USA, Colorado, state unilateral); 1.83/1000 (United States, State of Washington); and 3/1000 in (Philippines).[2]

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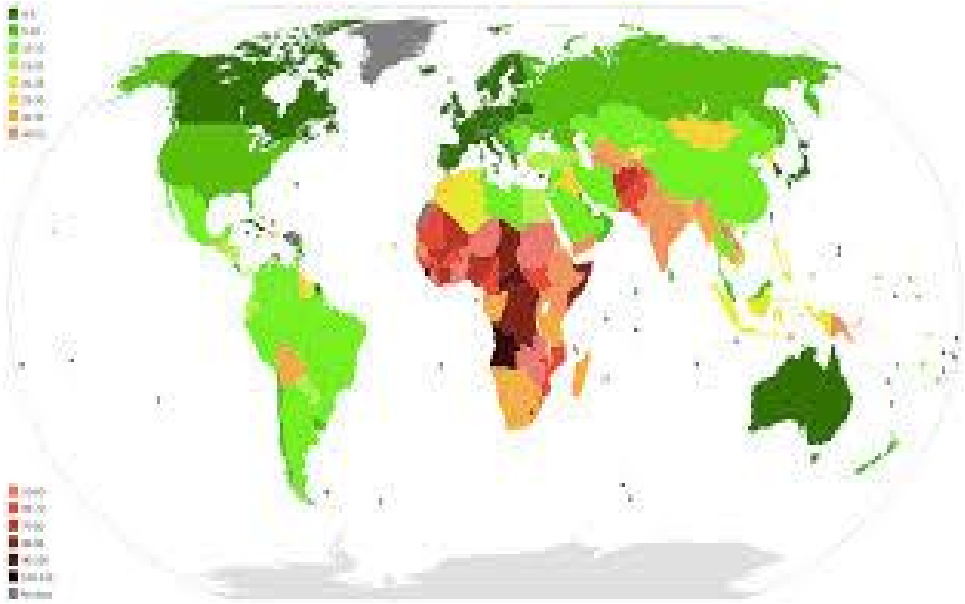


Universal Neonatal Hearing Screening (UNHS) is followed in developed countries for the early detection of hearing loss. It involves the use of objective testing methodologies (usually oto acoustic emission (OAE) testing or automated auditory brainstem response (AABR) testing) to screen the hearing of the whole population of newborn in a particular target region.[4]

Targeted neonatal hearing screening is selective hearing screening in which only a specific population within a region are screened (NICU neonates or patients coming under JCIH criteria).

Present scenario :

OAE is used as a screening tool in most countries while AABR is coming into vogue in developed countries as primary screening tool. In India and China, TEOAE and DPOAE are the primary tools in first and second stage. In USA, TEOAE is used as a screening tool, while AABR is used in second stage. In Germany, AABR is used as the primary screening tool. In India both the levels are conducted in tertiary care hospitals as audiological facilities in primary care level are still primitive. In European nations, second stage is usually done at specialist audiologic centres.

US Preventive Services Task Force(USPSTF) in 1999 concluded that current evidence neither suggested implementation of universal hearing screening nor against .However the same organisation declared a landmark statement supporting the establishment of nationwide screening programs. The 1993 National Institute of Health (NIH) Consensus Statement and the 1998 European-Consensus Statement on Neonatal Hearing Screening are the other relevant consensus regarding policies governing hearing screening program.

Policy regarding Hearing screening in India is still in evolution. Prevalence of Hearing loss in NICU setting[3] is nearly 1% indicating urgent need for proper hearing screening programs.

Etiological factors for hearing loss.

Non-genetic causes (33.30 %) :

- Jaundice
- Embryopathies
- Toxaemia of pregnancy
- First trimester bleeding
- Infection
- Ototoxic drugs
- Rh incompatibility

Perinatal causes (10.8%) :

- Birth asphyxia
- LBW (<2.5 kg) or prematurity
- Malpresentation

Post-term

Post-natal causes (12.5%)

- Eruptive fevers
- Meningitis
- Hyperbilirubinemia

Traumatic

Cerebral palsy

Genetic causes

Congenital syndromes (5.4%)

Idiopathic (50.6%) [5]

Types of Hearing Loss :

Conductive hearing loss :

It is defined as hearing loss which occurs due to anatomic obstruction or atresia of outer canal or middle ear.

Sensorineural hearing loss :

It is defined as hearing loss which occurs due to pathology involving the eighth nerve or the inner and outer hair cells of the cochlea .

Auditory dyssynchrony :

It occurs due to pathology of the myelinated eighth nerve fibres or inner hair cells causing impairment in transmission of impulse.

Mixed hearing loss :

Combination of transient or permanent conductive hearing loss with sensorineural hearing loss .[6]

Transient conductive hearing loss :

It occurs due to accumulation of debris in the auditory canal.

Pre-lingual Hearing loss

It occurs when the onset of hearing loss manifests in early infancy causing impairment of the communicative ability of the child.

CONGENITAL HEARING LOSS :

Nearly 50 % cases with pre lingual deafness are due to genetic causes. There about 100 loci identified for genes coding proteins required for functioning of cilia, spiral ganglion and other components of the hair cell. Dysfunctional proteins have been identified in calcium- potassium homeostasis, stereo -cilia linkage, apoptotic signalling and mechano-electric transduction.

Genetic hearing loss could be syndromic (30 %) or non-syndromic (70%). There are about 350 syndromes associated with hearing impairment; one of the common causes of non-syndromic and genetic cause of deafness is connexin-26 mutation which is autosomal recessively inherited. Skin manifestations can occur with Connexin mutants resulting in a syndromic association **keratitis ichthyosis deafness (KID) syndrome** and palmo-plantar keratoderma with deafness

Mode of transmission of genetic causes is autosomal dominant in 22 % of cases , autosomal recessive in 75 % and X-linked in 3 %.[7]

Cochlear anomalies :

In cochlear anomalies, the severity varies depending on the exact time at which an insult occurs during embryogenesis and may have different manifestations.

Jackler Classification is used to classify cochlear dysplasias. It depend on the gestational age at which development of cochlea gets arrested.

Cochlear dysplasias can occur due to insults occurring at any point of time between third and seventh week.

1. Third week -Labyrinthine aplasia- complete (also known as **Michel's** deformity)
2. Fourth week - Cochlear aplasia
3. Fifth week - Common cavity to the cochlea and vestibule and cystic cochleovestibular anomaly (incomplete partition IP) type I
4. Seventh week- Mondini's dysplasia; Incomplete partition (IP) type II . [8]

AUDITORY DYSSYNCHRONY (AD) :

It could be congenital or acquired. While in other causes of SNHL, both OAE and BERA responses are abnormal, AD is unique in the sense that, while ABR is abnormal, OAE response is normal .

This indicates that outer hair cell functioning is normal while auditory nerve dysfunction exists. The site of lesion for AD include cochlear spiral ganglia, cochlear inner hair cells and the auditory nerve. Audiograms of children with AD vary from hearing in the normal range with difficulty in hearing in noisy background to profound hearing loss.[9]

Risk factors for AD :

1. Neonatal jaundice (> 20 mg/dL)
2. Birth asphyxia
3. Infections
4. Family history
5. Congenital neurological problems

GRADING OF HEARING LOSS :

Hearing threshold	
Normal hearing sensitivity	≤25 dB
Mild hearing loss	30-45 dB
Moderate hearing loss	50-65 dB
Severe hearing loss	70-85 dB
Profound hearing loss	90 dB and above.

Mild hearing impairment with 30 db is significant enough to impair normal communication. Profound hearing loss with hearing impairment in excess of 90 db are candidates for cochlear implant program.[10]

Physiology of hearing :

Phenomenon of hearing is a complex process. Sound energy transmitted as vibrations through air, strike on the tympanic membrane. Vibrations are transmitted through 3 auditory ossicles to oval window. Mechanical vibrations induce motion in cochlear fluid, thereby transmitting the intensity and frequency of vibrations. Sound vibrations causes scala vestibuli to displace inward, simultaneously causing outward displacement of scala tympani which is otherwise called the round window reflex.

Vibratory motion generates nerve impulse. Cochlear epithelium is composed of hair cells - about 16,800 in each ear. Hair cells those respond to frequencies above 2000Hz are located in basal turn of cochlea. Others are in middle and apex of cochlea.

Peripheral neurons of cochlea are distributed to hair cells beneath the basilar membrane. Each outer hair cell is innervated by many neutrons while each inner hair cell, by a single neuron.[11]

Auditory Pathway :

Cochlear nerve fibres which originates from spiral ganglion terminate in dorsal and ventral cochlear nuclei. Then the fibres decussate resulting in bilateral representation.

Auditory fibres ascend along the lateral lemniscus, reach the brachium of caudate colliculus synapsing with the medial geniculate body. From there, axons reach the primary auditory cortex seen around the sylvan fissure via the internal capsule.Decussation occurs across the trapezoid body.

Synaptic connections occur with dorsal trapezoid nucleus , nucleus of lateral lemniscus and nucleus present in caudate colliculus.[12]

Otoacoustic emission :

An otoacoustic-emission (OAE) is a inaudible sound that is produced from the inner-ear . It arises in the external auditory canal when the tympanic membrane receives vibrations transmitted in a retrograde manner, through the middle ear from the inner ear. When the inner ear gets affected, OAEs are not produced; hence it assumes clinical importance.

Mechanism

Cochlea acts as a amplifier and this function serves as the basis of OAE production.In the absence of external stimuli, this function is higher resulting production of acoustic emissions.

OAE is recorded via ear canal probe that is inserted into the ear canal. Click stimuli of a 80 dB level can evoke a robust Transient Evoked OAE response only if hearing threshold is more than 20 dB.

Normal emissions that are recorded in neonates are about 15-30 db range. Signal processing is not required to assess this output from noise and fully validated frequency-specific recordings can often be made in a few seconds. BERA requires a much complex process with electrodes so as to distinguish from background EEG out output.

2 types of OAEs include spontaneous oto-acoustic emissions (SOAEs), that does not require stimuli, and transient evoked oto-acoustic emissions (TEOAEs), that requires an stimulus to evoke emissions.

Types of OAEs

Spontaneous OAEs

Spontaneous otoacoustic emissions (SOAE)s are inaudible sounds that are produced without any evoking stimulus and are measurable with sensitive probes in the external ear canal. The sounds are frequency-stable between 500 Hz and 4500 Hz. The majority of the people do not hear their SOAEs; Some people (about 1-9%) however perceive a SOAE as tinnitus.

Evoked OAEs

Evoked otoacoustic emissions are currently evoked using three different methodologies.

1.**Stimulus Frequency OAEs** (SFOAEs) are assessed after application of pure tone stimulus.

2.**Transient-evoked OAEs** (TEOAEs) are evoked using a stimulus which could be tone or click evoked . Click response occurs due to a frequency of around 4 kHz, while tone burst occurs due to a single pure tone frequency.

3.**Distortion product OAEs** (DPOAEs) are elicited with 2 primary tones. Non-linear intermodulation occurs with both of the tones within cochlea generating new components of frequency, which can travel to the ear canal. Healthy ear canal distortion levels can be above 20 dB SPL.

Sensory transmissive loss occurs due to outer hair cell malfunction. Absence of the ‘amplifying function’ of cochlear apparatus allows dampening to remove most stimulus energy from the cochlear travelling wave and lowers the resolution of the cochlear imaging mechanism.

Sensory transduction loss occurs due to inner hair cell malfunction in activating the nerve fibres.

Clinical importance

OAEs are highly useful in newborn screening as they are easy to do in non-co-operative patients and the methodology is simple.

Method :

In OAE a probe is kept in the external auditory canal of the newborn. There should be no debris or mechanical obstruction blocking the ear canal. This commonly happens in < 48 hours due to vernix deposition. If the result is "refer" and mechanical block is suspected , the babies are re-examined after 2 days anticipating spontaneous resolution of debris. [13]

Brainstem evoked response audiometry:

Definition :

Brainstem evoked response audiometry (BERA) is done using audiological click stimuli eliciting brain stem potentials resulting in production of waves that are then recorded using scalp electrodes.. This method of hearing evaluation was first introduced by Jewett and Williston in the year 1971.

Procedure:

The stimulus either in the form of click **or tone** is transmitted to the ear via a transducer placed in a head phone. The wave forms of

impulses generated at the level of brain stem are recorded by the placement of electrodes over the scalp.

Electrode placement:

The conducting electrodes are kept over scalp. Care must be ensured that the surface of scalp is dry without oil. As per the routine configuration of ABR electrodes , one of them is kept on vertex and inverting electrodes placed over the ear lobe of the ear which is assessed or the mastoid prominence. Another electrode is kept on forehead for the purpose of earthing. This earthing electrode is necessary for proper functioning of the pre-amplifier.

After ensuring the baby is sleeping or is in quiet alert state, click stimulus is applied. We use 40 db and 70 db for screening**.** Impedance matching is done prior to the procedure.

After observing for the appearance of typical wave pattern , average sum of potential evoked is noted. The process is repeated with opposite ear.

1. Eighth nerves - waves I and II
2. Cochlear nucleii - wave III
3. Superior-olivary complex - wave IV
4. Nuclei of lateral lemniscus - wave V
5. Inferior colliculus - waves VI and II[14]

Wave v is the largest in size and the most easily identifiable wave in recording as sharp negative deflection

Equipment : RMS **BERA MARK 2 machine** was used

INTERPRETATION :

While interpreting BERA waves, amplitude , latency and interwave latency is noted. Amplitude measures the number of firing neurones , latency - the processing speed and interwave latency measures the time between peaks.

From 70 dB intensity recordings are made and the intensity is lowered. Wave V is noted with each lower intensity and the minimum at which it occurs is defined as **hearing threshold**

Finding suggestive of pathology :

1. Absent brain-stem response
2. Absolute inter-aural fifth wave latency
3. Wave I to V interpeak latency

Delayed and absent waves :

BERA waves represent a summated activity of large populations of neurones firing in synchrony. Delayed waves occur if there is uniform delay in neutron firing.

Absent waves occur when the delay is non uniform due to temporal dispersion.

LATENCY :

Wave I : 1.5 seconds

Wave III : 3.57 seconds

Wave V : 5.53 seconds[15]

PROCEDURE :

1. 10 - 20 system is the standard that is used world-wide for placing electrodes.
2. Standardised silver and silver chloride electrodes are commonly used.
3. Frequency of click is 10/ second
4. A masking sound of about 40 dB is applied on the contralateral ear.
5. About 2000 to 4000 responses of electrical activity is noted. In newborn usually 2000 responses are used and its average sum is noted.

Behaviour response audiometry :

It involves presenting sounds and observing their responses. Usually overt responses to controlled auditory stimuli are assessed. It is commonly used in 6 - 9 month age group. It is done using standardised bell, rattle or noise- making toy.

It is useful in following settings.

1. In neurologically immature babies where ABR cannot be reliable.
2. To provide information about low frequency hearing loss.
3. To demonstrate the benefit of hearing aids.[16]

NICU SCREENING PROTOCOL (NNF Guidelines) :

- NICU

a) AABR is the hearing screening method of choice for all NICU infants; OAE in settings where AABR is unavailable.

b) Initial screen: Each ear is attempted twice to collect valid recording

c) Second screen: Should be done in subsequent day. Such attempts can be made upto 2 times

d) Maximum: Avoid doing hearing screening more than twice

e) Any neonate needing more than 5 days of NICU care must be screened with ABR, so as not to miss sensorineural loss.

f) ABR failures require confirmatory BERA testing.[17]

COCHLEAR IMPLANT PROGRAM - INDICATION

Cochlear implant devices can be used for children of 12 months and older.

CI evaluation of a in infant age group should include the following:

Behavioural audiometry (i.e., Visual Reinforcement Audiometry),

OAEs,

ABR

ASSR, Auditory steady state response

Tympanometry, and

Acoustic reflexes.

Positive OAEs with absent ABR or ASSR and absent reflexes should generate suspicion of AN/AD.[18]

JOINT COMMITTEE ON INFANT HEARING :

High risk criteria of newborn was devised by JCIH, an Association with representatives from American Academy of Pediatric, American Speech Language Hearing Association and American Academy of Ophthalmology and Otolaryngology .

It propagates EHDI- **Early Hearing Detection and intervention** program with emphasis on 3 points

1.Early detection - soon after birth

2.Follow up screening

3.Early intervention

Golden rule of hearing screening is 1-3-6.

1.Universal screening of all newborn by one month

2.Confirmatory testing by ABR for all screened positive

3.Early intervention by 6 months

Reach of hearing screening has improved greatly in developing countries with coverage reaching upto 92 %.[19]

NATIONAL PROGRAMS

1.NATIONAL PROGRAMME FOR PREVENTION AND CONTROL OF DEAFNESS :

Early identification, diagnosis and treatment of ear problems responsible for hearing loss and deafness is one of the important components of this program.Rehabilitation of deaf children is included in this program. It mainly focuses on training of ENT surgeons and audiologists at primary and secondary care level. Sensitisation of Paediatricians regarding early screening is done by means of training modules.[20]

Rashtriya Bal Swasthya Karyakram (RBSK) is an healthcare initiative aiming at early intervention for children from birth to 18 years to cover 4 'D's which includes Defects at birth,Diseases, Development delays including disability.Deafness is included under the 30 ailments covered in this study.Early intervention centers are to be established at the District Hospital level across the country as District Early Intervention Centers (DEIC). The purpose of DEIC is to provide referral support to children detected with health conditions during health screening, primarily for children up to 6 years of age group.

REVIEW OF LITERATURE

The relevant studies done in the area of hearing screening in both India and other countries are listed below.

- A descriptive study was done in the year 2014 in ENT department, CMC Vellore by **Achamma Balraj et al** in which 9448 babies were screened and followed up. Period of this study was 11 months. 164 had suspected hearing loss and on subsequent follow up, 39 had deafness
- Using BERAphone, a portable BERA equipment, 2 stage screening process was done. Newborn babies suspected to have hearing loss then underwent confirmatory testing using ASSR auditory steady state response audiometry. In addition, serological testing for TORCH infections (6 were tested positive), and *connexin gene* (1 proved positive) mutation was done. Neonatal hearing screening using BERA was identified to be a feasible service. The estimated prevalence of confirmed hearing loss (1.4) was comparable to that in literature (1.6).
- Comparative evaluation of BERA and TEOAE as screening modality for hearing impairment in neonates was done by **Mathur et al** in Lady Hardinge Medical college in the year 2007. The study group of 200 randomly selected neonates was subjected to TEOAE

and BERA (400 ears). In all TEOAE failures oto-endoscopic cleaning was done to remove debris (52) and a repeat test was done after suction cleaning of blocked external auditory canal (EAC). Pass rate was 92 %. In <48 hr age group, it was 55 % suggesting high prevalence of obstructed ear canal.

- Feasibility of a 2 stage hearing program was first assessed by **Vaid et al**. A neonatal hearing screening programme has been established in Pune, India. From August 2005 to August 2007 a total of 2621 babies were tested using otoacoustic emissions (OAE), followed by second stage brainstem evoked response audiometry (BERA) for those who were referred on the second OAE testing.

249 were referred on the second OAE testing and of these, only fifty two came back and were further evaluated using BERA. 15 of these fifty two babies were found to have a significant hearing loss.

- Comparison of distortion product otoacoustic emissions and automated auditory brainstem response in the same ear of the babies in neonatal unit was studied by **Wahid et al**. AABR has a higher passing rate as compared to DPOAE. However, the use of both instruments in the screening process especially in NICU will be useful to determine the infants with **ANSD w**ho may need different approach to management. Therefore, a protocol in which

newborns are tested with AABR first and then followed by DPOAE on those who fail the AABR is recommended.

- TEOAE was compared with BERA by Granell in terms of accuracy, duration of testing with the results favouring BERA in terms of pass percentage. 860 newborns were screened with OAE and **2300 were done with evoked response audiometry.** Median time for performing BERA was 265 seconds.
- 2 stage hearing program in Indian population was studied by **Bansal et al** - OAE at 48 hours after birth and those cases which failed was screened with BERA. 2659 babies were screened. Pass percentage was 77.5 percent.
- A number of studies were done on high risk cohort. **Hess et al** did a study on high risk screening done with BERA and TEOAE. 942 neonates were screened and 835 passed. The prevalence of deafness came out to be 1.4 %.
- Deafness in German population was analysed by **Ohi et al**. JCIH criteria was used to identify high risk population and both BERA and OAE was used. Conductive deafness was noted in many cases with craniofacial anamolies. 1455 babies were screened and hard of hearing was detected in 4.55 % of cases. 60 cases were identified with deafness.

- 2 stage AABR testing was analysed by **Van s'raaten et al** . More than two thousand babies were screened and referral rate was identified to be 3 %. This prospective study collected data on 2513 neonates who were discharged from NICU. NICU graduates with JCIH risk factors were included in a 2 stage AABR hearing screening programme. Conventional ABR was used to establish a diagnosis of CHL.

A total of 2513 newborns were enrolled in the programme with a median gestational age of 31.6, a median birthweight of 1450 (range 510-4820) g. In 25 cases, parents refused screening. 4 out of 2513 newborns were lost to follow up**;** 2484 newborns have been tested initially. A participation rate was 98 percent (2465/2513) was obtained for the whole screening programme.

After a median postmenstrual age at the first test of thirty three weeks, a pass rate of 2284/2484 (92%) was arrived at the first stage. The rescreening compliance after the first test was about 92% (184/200).Among those cases, 77 babies were referred for BERA.Of the 77 referrals, fourteen had normal screening thresholds, fifteen (19.5%) had unilateral conductive hearing loss and 48 (62.3%) had bilateral conductive hearing loss. The prevalence of unilateral conductive hearing loss was 0.6% (15/2484) and of bilateral conductive hearing loss was 1.9% (48/2484)

- **Yoshinaga** et al studied the benefits of early screening. 46 children with early identification of hearing impairment were compared with 69 diagnosed late. 23 children in the first group showed significant improvement in language abilities while in the 13-18 month period. When the same cohort was followed up between 19-24 months, 28 children showed significant improvement.
- **University of Washington** research is one of the largest program till date. Nearly 7000 babies were screened with TEOAE, DPOAE and ABR. ABR had lower referral rate.
- **Rhode Island Hearing Assessment Program** was one of the earliest analysis of a state-wide hearing screening program. 11 babies with congenital hearing loss were detected. Prevalence of deafness was 2 %. Mean age of identification of hearing loss was 3.5 months. 8 maternity hospitals had enrolled in this 4 year project.
- In BJMC, Ahmedabad **Amitkumar et al** did a similar study comparing AABR and OAE.TEOAE referred patients were further screened by Automated AABR. About 284 patients passed OAE and 11 babies were identified with hearing loss. Low birth weight, hypoxia , jaundice were identified as risk factors.

- As a pilot study **C.S Gohill et all** studied 3 stage hearing protocol. 300 babies were screened with OAE. 24 babies were referred for 2nd OAE. 18 babies were detected who were then referred for subsequent BERA examination. 12 failed BERA test. Incidence of hearing loss was 8 % as per this study. While OAE is accepted as a low cost screening tool, BERA was identified as the gold standard for hearing loss.

- Incidence of deafness in Chinese was assessed by **Xu et al** who performed 2 stage hearing study in Shangai NICU population.Three thousand high-risk neonates were screened at Children's Hospital in Fudan University. They were randomised and then directed to two different screening procedures separately.

The first procedure consisted of DP-OAE alone and the second consisted of first stage DPOAE combined with the AABR. The combined DPOAE plus AABR screening technique showed a total referral rate of 5.03%, a false-positive rate of two percent and a total false-negative rate of about 0.06%. Comparisons of the referral rate, false-positive rate , sensitivity and false-negative rate of the two hearing screening program protocols (DPOAE alone and combined DPOAE/AABR) revealed significant differences .

Ninety one infants (3.03% of the NICU graduates) who failed the combined DPOAE plus AABR screening were confirmed to have hearing impairment. Of the twenty, two babies who passed DPOAE screening but failed to clear the AABR screening had a profound hearing loss based on classic brainstem response audiometry.

- **Meier et** al compared ease of use and accuracy of multiple equipements. OAE, the Fischer-Zoth's Echoscreen-TDA, and two AABR screening equipments, the Algo 3 and the MAICO's Beraphone MB11, were tested prospectively.Transiently-evoked oto-acoustic emissions (TEOAE) and also distortion-product otoacoustic emissions (DPOAE) were assessed in both ears of hundred and fifty newborns from nursery using the Echoscreen-TDA. 150 babies were split into 3 equal groups and assessed with each of the above said equipment.

Tests were done on day 3 of life. The median test duration in one ear was thirty seconds for EOAE measurements and four to five min for AABR recordings. Expense for the disposables and machine were least for the Echoscreen and MAICO's Beraphone MB11, respectively and maximum for the Algo 3.

With ninety eight% the rate of passing was maximum for AABR recordings using the Algo 3 and least with ninety two percent for

Automated ABR recordings using the MB11-Beraphone, but differences were statistically insignificant.

- 7 hospitals were involved in a multi centric study by **Johnson et al** which were already following 2 stage hearing screening protocol with OAE and AABR were enrolled. More than eighty thousand neonates were involved in this study.

Those babies with OAE-refer but have cleared automated-ABR in atlas one ear 1524 were enrolled in the study. Details about risk factors of hearing loss were assessed in these babies.In about 64 % of participants study was done after 8 months of age.

There was SNHL in 21 infants who passed automated ABR but failed in OAE. 23 (seventy seven percent) of the ears had mild hearing loss (average of 1 kiloHz, 2 kiloHz, and 4 kiloHz < or =40-db hearing level). 9 (43%) infants had bilateral as opposed to unilateral loss, and eighteen (86%) infants had sensorineural hearing loss as opposed to conductive hearing loss.

If all participants were screened for hearing impairment using the 2-stage OAE/A-ABR newborn hearing screening protocol currently used in many hospitals, then approximately 23% of those with permanent hearing loss at approximately 9 months of age would have passed the A-ABR. The study also shows the importance for continued follow up of hearing status during childhood.

- **University of Bordeaux** did a study in determining the correlation between brainstem response BERA and behaviour response audiometry BOA . There was no behavioural audiometry response at hundred dB when there was no brainstem response at 100 db, in 84.2% of cases, thus resulting in a k coefficient of 0.72.

The difference between the ABR and the BA thresholds, when there were response with BERA was equal to or less than ten dB in 67% of cases and equal to or less than twenty dB in 95% of cases**. (2) Longitudinal study (fifty children).** Hearing threshold determined via behaviour observation audiometry was similar (within a difference of less than 10 db) when compared between 4 to 18motnh period and 3 to 4 years at the frequencies of 1000, 2000 and 4000 Hz and in 78% of cases at 500 Hz.

Both of these analysis provide evidence to the validity of the behavioral audiometry measurements at an early age using the above mentioned protocol.

- **Ulusoy et al** studied a total 11575 neonates that were either born in Çorlu State Hospital, located in Turkey, between September 2009 and November 2012 were included into the study. Automated TEOAE Transient Evoked Otoacoustic Emission test and

AutomatedAuditory Brainstem Response (AABR) were used as screening procedures.

TEOAE is the initial screening test. Failures are repeated after 15 days. Subsequent testing are done with ABR at ENT centres.Nearly 600 babies failed among the fifteen thousand neonates who took the test (5.12 %). Those neonates were referred for ABR. Out of these 593 neonates, four hundred and seventy had passed the diagnostic ABR test at the referral center. Unilateral & bilateral sensorineural hearing impairment (SNHL) was detected at fifteen & seven babies respectively;Consanguinity and family history of hearing loss were some of the risk factors present in the 22 babies screened positive.

- In Indian population, **Mishra** et al estimated the prevalence of deafness in < 2 age years as 1 %. 1101 infants were screened and 126 were suspected to have hearing loss. High risk group among this population was 50 %. 12 children were identified with deafness. It was found out that positive predictive value of OAE increased with multiple tests.
- **Dhingra** et al compared Behaviour response audiometry(BOA) with AABR and OAE and Auditory steady state response ASSR. BERA was taken as reference Sensitivity of AABR and BOA was nearly the same (94%). OAE had higher sensitivity (97%). But

OAE had much lower specificity 59%. Cost analysis was done. BERA (Rs 200/ test) was more expensive than OAE(Rs 40) and AABR(Rs 40) despite re-using scalp electrodes. BERA equipment (14 lakhs) was more expensive than OAE (2.5 lakhs). BERA, AABR and ASSR was done using the same equipment. Cost included disposables, cotton, conducting gel etc.

- Influence of prematurity as a risk factor was studied by **Kilic et al** in Turkey.

  29 premature babies were screened with BERA and were compared with 29 Term babies in the control group.

  While the study failed to prove prematurity as a risk factor , mode of delivery, low APGAR score and neonatal jaundice were recognised by this study.

- Safety of Cochlear implant program in infants less than 12 months was studied by **O'connell et al**. The study showed the difference in post operative complications in less than 12 month age group and 12 to 18 month age group was statistically insignificant paving the way for early interventions .This makes early identification programs crucial for identifying candidates for early surgery.

- Impact of early identification programs was evident by study done by **Lammers et al .** Mean age of identification came down from 2.4 years to 1.2 years. Percentage of early implanted babies

increased from 9 % to 37 %. Thus indicationg that hearing screening programs have a major influence in improving the mean age of hearing implanted infants.

- A series of studies done by **Gordon of et al** revealed re-organisation of auditory cortex by cochlear implant. Early intervention facilitates auditory development in thalamo-cortex .
- Referral rates as well as prevalence of deafness in newborn population was done in Chennai by **Jaya et al.** Thousand and four hundred babies were screened by OAE .Using ABR second stage screening was done.

Three hundred and eleven babies were referred by first stage. 31 babies were referred for subsequently for further testing. Ultimately two babies were identified with profound hearing loss. Both high risk and newborn population was studied in this landmark study.

- Bera changes specific to hyperbilirubinemia were studied. Loss of peaks, latency of third and fifth wave and elevated hearing threshold were noted by **V.K AGARWAL et al .**

These findings were reversible when BERA was done after 6 months indicating some of the insults due to bilirubin encephalopathy were transient. This also highlights the need for serial testing and multi-staging of hearing screening protocol rather than a single stage program.

- Auditory neuropathy spectrum disorder was identified as discrete entity by **Kaga et al** . Three distinct subclasses were found.

Normalisation of hearing occurred in first type .Second type developed profound hearing loss. Third type resembled auditory neuropathy of the adult hence termed true auditory neuropathy.

- Prognosis of cochlear impants in these cases were studied by **Breneman et al** and were found to have similar success rates as that of other children with sensorineural hearing loss. They showed poor response to hearing aids.
- Mutations in Connexin twenty six and thirty were identified as cause of hearing loss in population with SNHL in Sicily . Sixty eight out of One hundred and ninety six patients were found to have this genetic mutation.

This proves that genetic mutations is a common cause of non-syndromic hearing loss and connexin mutations contribute to large part of this genetic cause

STUDY JUSTIFICATION

Importance of screening for major diseases in newborn is on the rising trend.As mentioned earlier, in February 2013, Rashtriya Bal Swasthya Karyakram (RBSK), a new initiative aimed at screening over 27 crore children was launched. Since deafness is included under this, early identification of hearing loss is need of the hour. Children thus diagnosed with illnesses shall receive follow up including surgeries at tertiary level, free of cost under National Rural Health Mission (NRHM). Early screening will supplement cases to this program.

Optimisation of hearing screening protocols is essential. While OAE remains the ideal tool in low resource settings, BERA screening is needed to rule out auditory nerve dysfunction. OAE has a higher referral rate due to higher false positive results. This leads to parental anxiety and need for multiple visits to tertiary care centre.

BERA screening is limited by its expense, need for trained audiologist for testing and validation. Noise free environment with insulation from electrical disturbances and proper power connections are necessary for obtaining a valid result.

Though a number of studies have been done in other countries regarding hearing screening protocols, data regarding Indian population with regards to high risk screening is lacking.

This study has been envisioned to bridge that gap and to add data to our existing pool of resources, to make an informed decision regarding choice of hearing screening tool, protocol and the man power.

Burden of Hearing impairment is expected to rise due to increase in number of preterm babies and babies who have received intensive care.

AIMS AND OBJECTIVES

AIM :

To compare the diagnostic ability of Oto-acoustic Emission and brainstem evoked response audiometry in hearing screening of high risk infants.

OBJECTIVE :

1. To determine the ideal hearing screening tool in high risk newborn.
2. To study the referral rate of OAE and BERA in populations with the following risk factors- prematurity, low birth weight, neonatal jaundice and birth asphyxia.
3. To reduce false positive rate of OAE by 2-stage hearing program.

HYPOTHESIS

Null hypothesis assumed in this study include

1. There is no difference in diagnostic ability of OAE and BERA.
2. There is no correlation between parameters like age, sex, neonatal jaundice, sepsis, birth asphyxia, ototoxic drugs and Hearing loss

SUBJECTS AND METHODS

Study Design	:	Cross-sectional study
Place of study	:	Newborn department, ICH and IOG
Period of study	:	March 2015 to September 2015
Study population	:	High risk newborn (JCIH criteria)
Sample size	:	144 based on prevalence in high risk infants

Approval was obtained from Institute ethical committee. Written consent was obtained from parents in a pre- structured proforma, prior to the procedure.

Equipment :

BERA	:	RMS BERA mark 2 machine was used.
OAE	:	Neurosoft machine (TEOAE) was used.
Disposables	:	Scalp electrodes, cotton, conducting gel.

Inclusion criteria :

High risk neonatal population as defined by JCIH criteria.

Risk factors that are seen with hearing impairment

(JCIH risk criteria of 2007)

- Concern from family members regarding hearing loss
- Positive Family-history of hearing impairment
- Neonates requiring NICU care > 5 days, including administration of
    - Ototoxic medications
    - Assisted ventilation
    - Hyperbilirubinemia requiring exchange transfusion
- Postnatal infections (meningitis, sepsis)
- In utero infections, including TORCH- CMV, herpes virus, rubella, syphilis, and toxoplasmosis
- anomalies of the pinna or ear canal,cleft palate or lip ear tags, ear pits, or temporal bone anomalies and other craniofacial anomalies.

Syndromic causes of hearing loss

- Neuro-fibromatosis
- Osteopetrosis
- Waardenburg syndrome
- Alport syndrome
- Jervell syndrome
- Lange-Nielsen syndrome
- Pendred syndrome
- Usher syndrome

- Treacher-Collins syndrome

All high risk babies discharged during study period were included in the study.

Parents or grand-parents of the babies were informed about the study and consent was obtained**.**

Details of the baby including name, gestational age, sex, birth weight, address and contact number were noted. Significant antenatal history and course of NICU stay including treatment details of birth asphyxia, Neonatal jaundice and ototoxic drugs used. Family history of hearing loss was probed.

DEFINITIONS

LOW BIRTH WEIGHT (LBW)

Birth-weight <2500 gm

VERY LOW BIRTH WEIGHT (VLBW)

Birth-weight < 1500 gm

PRETERM

Gestational age of less than two hundred and fifty nine days or thirty seven weeks

TERM

Gestational age of Two hundred and fifty nine to two hundred and ninety three days or thirty seven completed weeks to forty two completed weeks 37 to less than 42 completed weeks.

Neonatal hyperbilirubinemia was defined as that requiring exchange transfusion or phototherapy more than 5 days.

Birth asphyxia:

Apgar score of less than 7 at 1 minute of age

Family history of hearing loss and maternal concerns about hearing loss if any were noted.

Ototoxic drugs included were amikacin, gentamicin and loop diuretics.

Hearing loss defined as hearing assessed by brain-stem response audiometry to be less than threshold levels for normal hearing.

STUDY MANOEUVER

A detailed examination was done looking for craniofacial anomalies especially ear anomalies like microtia, pre-auricular tags or pits.

Family history of hearing loss and maternal concerns about the neonates hearing was noted.

Details were noted in the proforma; the screening results were filled in by the audiologist . OAE result was obtained separately from routine screening program and was added to data.

OAE was done with complete automated screener which displayed the results as either “PASS” or “REFER”. Parents of babies which failed were explained about the prognosis and the need for further testing.

BERA was done with RMS^{TM} screener. Waveforms were observed and validated by audiologist in real time. Waves were stored in hard disc for future reference.

OAE was done in 144 babies in IOG by routine screening by the audiologist . All babies were referred to ENT department ICH for further testing. BERA was performed by trained audiologist hired for this study. OAE failures were asked to return **for repeat testing** to rule out blockage of ear canal.

Newborn ABR :

- Room must be noise-free, with plenty sound absorbing surfaces. Proper Earthing of electrical supply is vital. This must be checked before establishing the room with electrician. Earthing can be ensured by asking the parent to keep her legs on a wooden table.
- Preparation time of newborn is about 10 minutes. We did the study with the baby in quiet alert state soon after being breast fed. Older babies can be sedated with Triclofos syrup if needed
- Since skin of newborn peels easily one should rub alcohol gently before placing electrode. Generic alcohol is commonly used but Nuprep is preferred for this purpose.
- Conducting gel should be applied liberally to the electrode and fixed to skin with micropore plaster. Regular white plaster should be avoided.
- Average sum of 2000 electrical responses should be electrode. This ensures generation of a proper waveform.
- The electrodes should be wiped off the gel and immersed in a cup of distilled water to maintain its conducting property

Babies who failed in BERA were asked to review after 2 months for confirmatory BERA testing.

2 Contact numbers were obtained from both OAE and BERA referrals. OAE failures were asked to return for repeat OAE testing after 1 month.

BERA failures were informed about the prognosis and the need for repeat testing at 3 months and the importance of early intervention. Further testing was advised at Audiology department at MMC after 2 months. Details of the cases were given to paediatric ENT department at ICH.

STATISTICAL ANALYSIS

The diagnostic ability of hearing loss among the children was diagnosed by BERA Vs OAE. The ability of the test was identified and inferred by McNemar paired Chi-square test (χ^2) test. The diagnostic ability was done screening test and interpreted the results by Likelihood ratios.

The factors which are correlated with deafness were interpreted by Pearson chi-square (χ^2) test. The significance of the measurable characteristics like age and NICU admissions were compared between the diagnosed subjects by students' "t" test. The above statistical analysis and interpretations were performed by an **appropriate statistical package**. The p- values less than 0.05 were considered as statistically significant ($P<0.05$).

RESULTS

Comparison of predicting percentage

The three diagnostic tests were analyzed and tabulated.

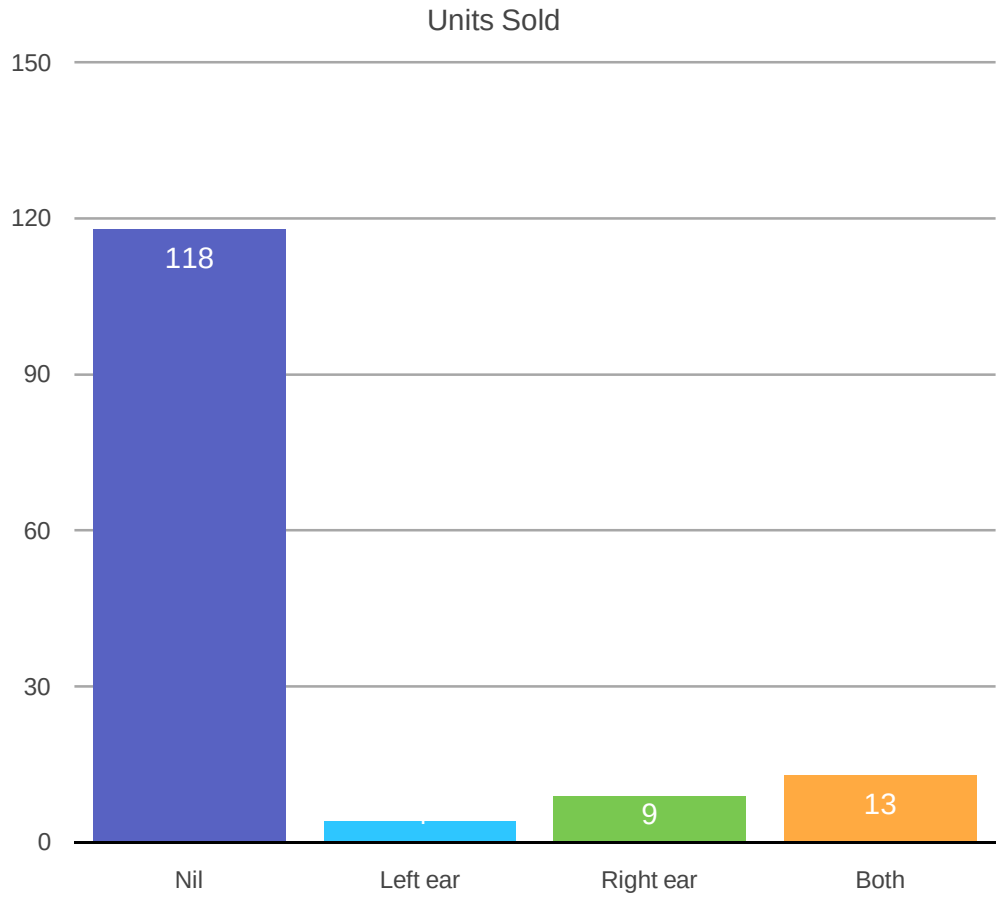


Table-1.Classification of hearing loss in the three diagnostic tests:

Hearing Loss	OAE		BERA 90 db		BERA 40 db	
	Frequency	%	Frequency	%	Frequency	%
Nil	118	81.9	138	95.8	138	95.8
Left ear	4	2.8	0	0.0	1	0.7
Right ear	9	6.2	0	0.0	0	0.0
Both	13	9.1	6	4.2	5	3.5
Total loss	(26)	(18.1)	(6)	(4.2)	(6)	(4.2)
Total	144	100.0	108	100.0	144	100.0

The total hearing loss predicted by OAE was 26 (18.1%) and the other two tests had predicted as 6(4.2%) each**. But BERA 90, predicted 6 ears of both and the same was considered as Gold standard.**

Among 26 tested positive with OAE, 13 had hearing loss in both ears. 13 had unilateral hearing loss with 9 in right ear and 4 in left ear.

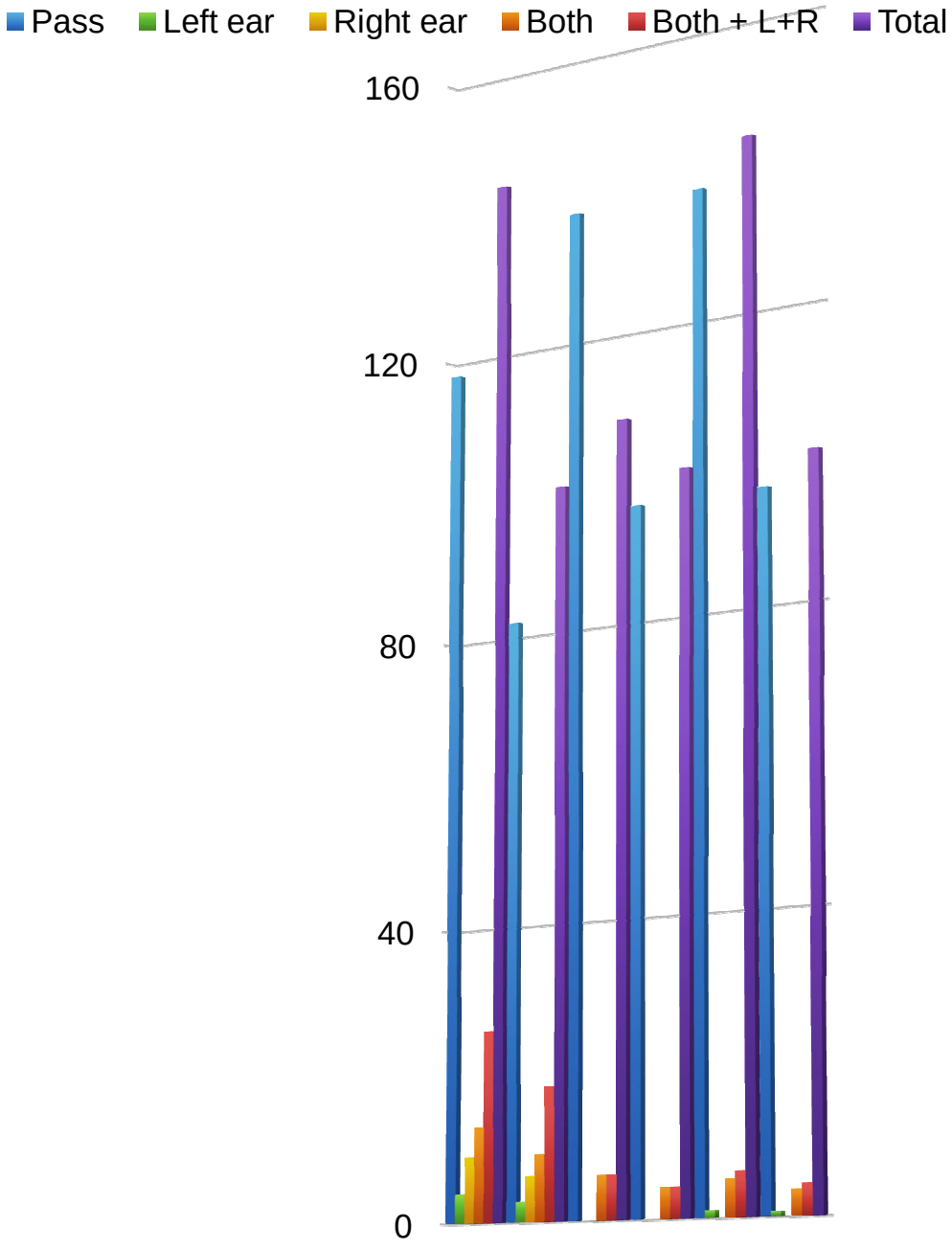

Pass
Left ear
Right ear
Both
Both + L+R
Total
160
120
80
40
0

Table-2. Comparison of predicting positive Percentage of OAE and BERA 90:

OAE	BERA 90			χ^2_{paird}	df	Significance
	Yes	No	Total			
Yes	1	25	26	12.033	1	P<0.001
No	5	113	118			
Total	6	138	144			

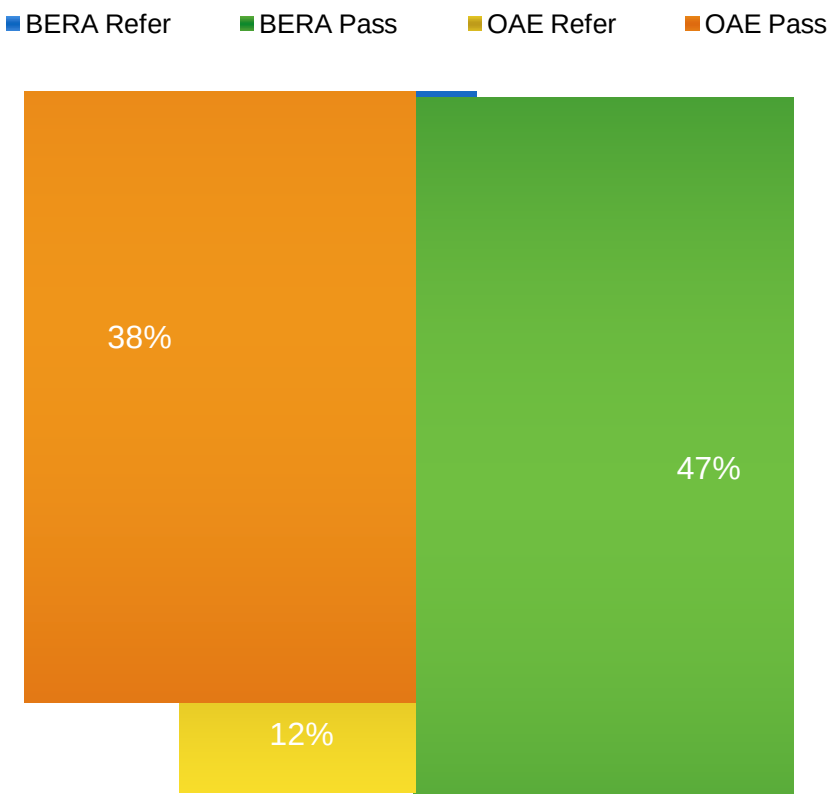
The percentage of positive prediction by OAE (18.1%) was significantly greater than the BERA 90 (4.2%) positive prediction (P<0.001).

Diagnostic ability of prediction:

The predicting capacity of the tests was analysed by screening tests with reference to the BERA 90 as Gold standard and OAE diagnostic test. The results of the test were interpreted by positive and negative likely hood ratio.

Table-3: Sensitivity and specificity of the tests:

OAE	BERA 90(Gold Std)		Total
	Positive	Negative	
Positive	1	25	26
Negative	5	113	118
Total	6	138	144



The sensitivity of the test (OAE) was 16.7% and specificity of the test was 81.9%.

Likely hood Ratio + = and Likely hood Ratio - =

LR+ = .923 and LR- = 1.02.or 102%.

The interpretation of LR+ was " A +ve result on OAE is .923 times more likely to occur in a subject with hearing loss as compared to a subject who does not have hearing loss".

The interpretation of LR- was " A -ve result on OAE is 1.02 times more likely to occur in a subject who really has hearing loss as compared to a subject who does not have hearing loss".

At the context of low prevalence rate of hearing loss the above interpretations are acceptable and BERA 90 has more diagnostic ability than the OAE.

The age of infants in day and NICU stay were compared between positive and negative with respect to BERA-90 db and OAE.

Table- 4: Comparison of positive and negative of BERA and OAE of infants' age and NICU stay:

Test	Variable (days)	Negative		Positive		Difference b/w means	"t"	df	P
		Mean	SD	Mean	SD				
BERA 90 db	Age	16.6	6.0	20.3	9.7	3.7	1.428	106	P>0.05
	NICU	11.3	4.2	15.3	6.6	4.0	2.240	106	P<0.05
OAE	Age	16.5	6.0	18.1	7.0	1.6	1.156	106	P>0.05
	NICU	11.3	4.4	12.4	4.4	1.1	1.184	106	P>0.05

In the above table -4 states the positive and negative of subjects age and stay at NICU with respect to BERA 90 and OAE. The mean ages of Negative and positive of BERA 90 was not statistically significant (P>0.05). But the mean duration of NICU stay BERA positive (15.3±6.6 days) was statistically significantly greater than the negative mean duration of 11.1±4.2 days P>0.05). In respect of OAE neither age nor NICU stay was statistically significant (P>0.05)

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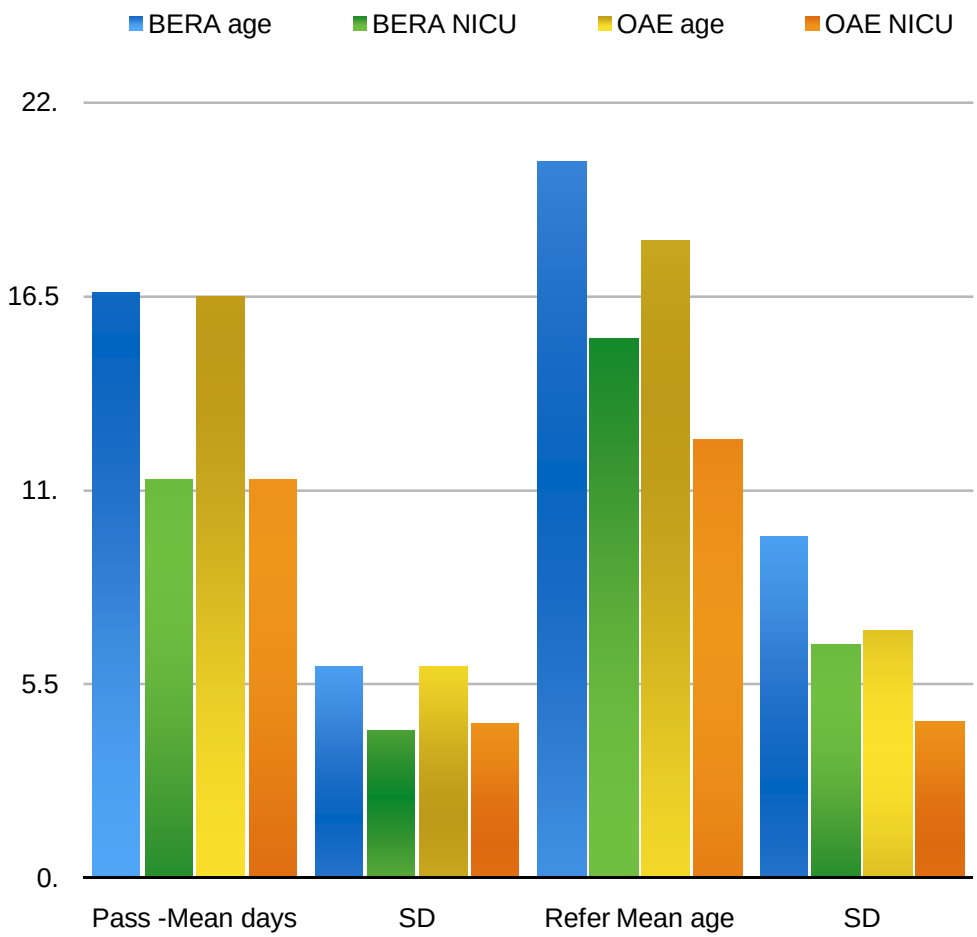
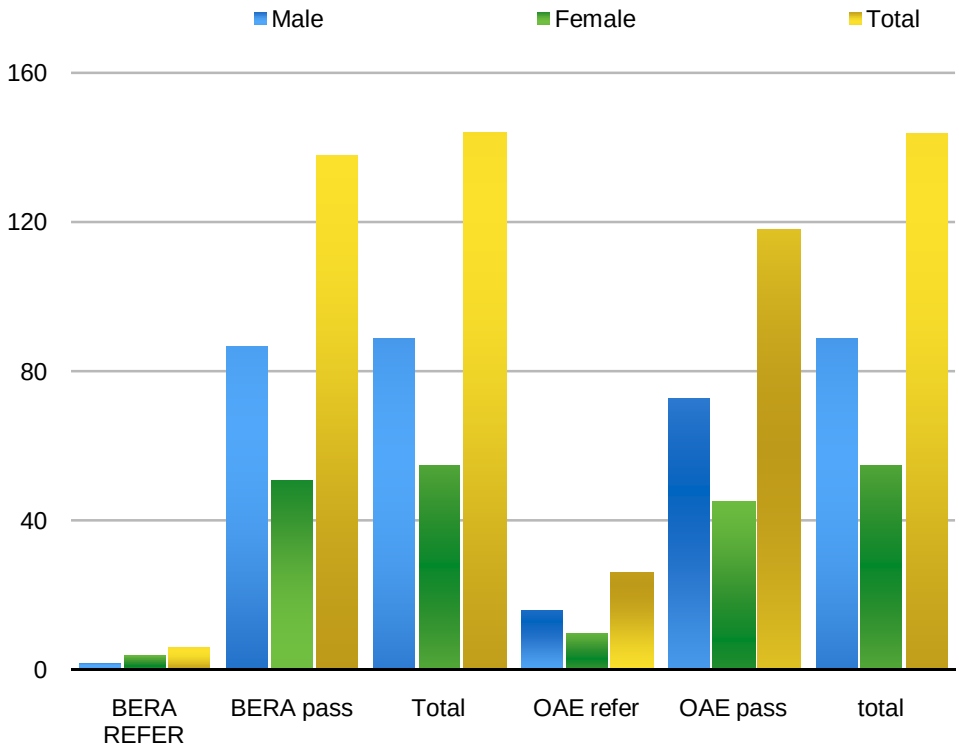

BERA age
BERA NICU
OAE age
OAE NICU
22.
16.5
11.
5.5
0.
Pass -Mean days
SD
Refer Mean age
SD

Factors associated with the hearing loss diagnosed by BERA 90 db and OAE:

The factors like sex, neonatal jaundice, birth asphyxia, ototoxic drugs, sepsis, Birth weight and term of the infant were studied to identify the association between BERA and OAE.

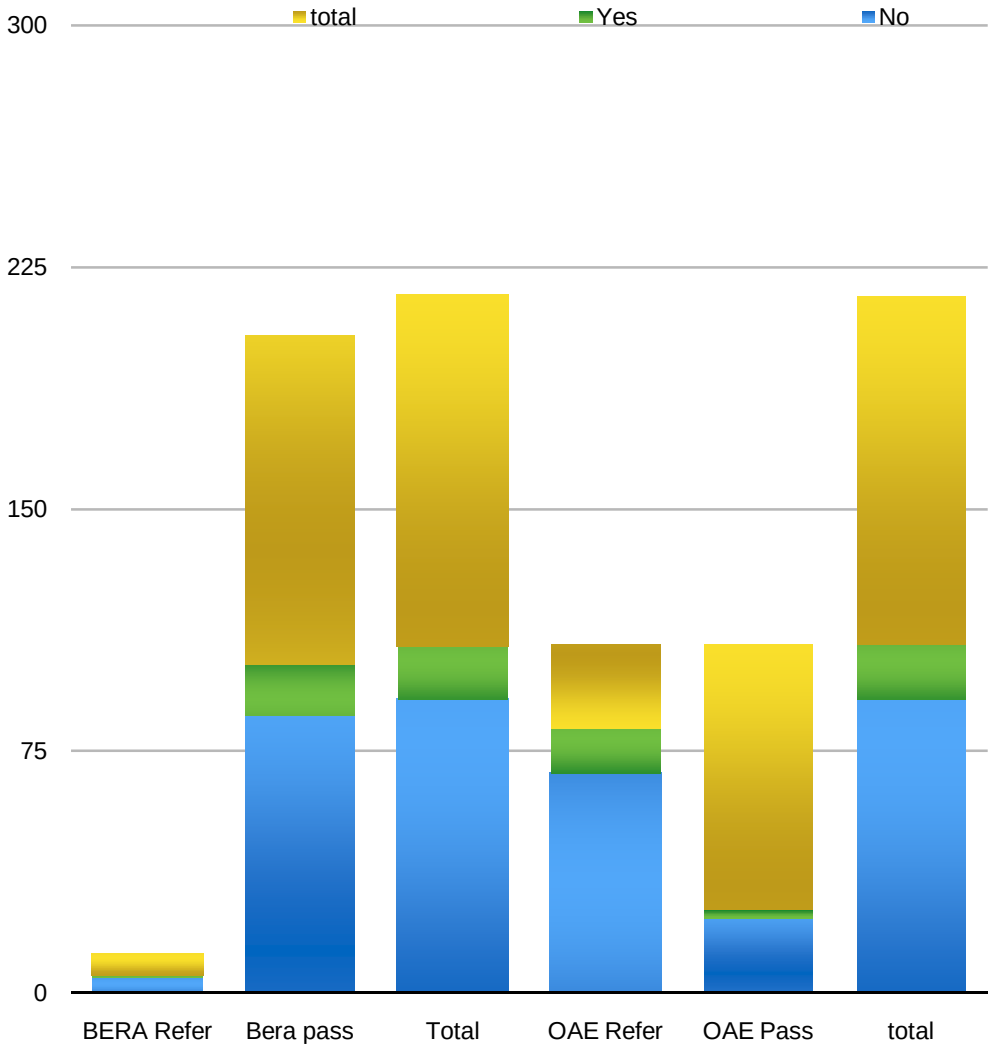
Association between Hearing loss and sex:



Sex	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
Male	2	87	89	χ^2=.000	16	73	89	χ^2=0.004
Female	4	51	55	df=1	10	45	55	df=1
Total	6	138	144	P=1.00	26	118	144	P=0.500

Table -5 shows the association between sex and hearing loss screened with BERA 90 and OAE. The results revealed that there was no significant associated established either positive or negative in both tests (P>0.05)

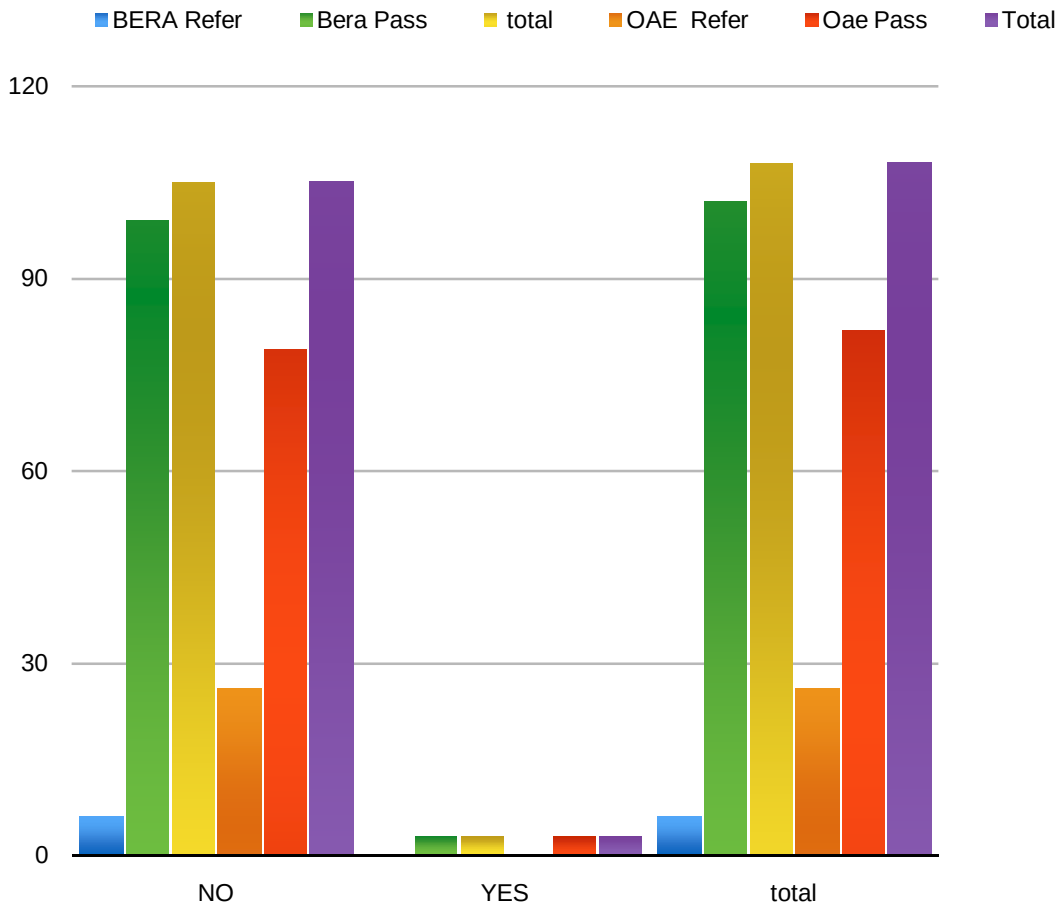
Association between hearing loss and NNH:



NNH	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	5	119	124	χ^2=.000	23	101	124	χ^2=0.000
Yes	1	19	20	df=1	3	17	20	df=1
Total	6	138	144	P=1.00	26	118	144	P=1.00

Table -6 shows the association between Neonatal jaundice and BERA 90 and OAE. The results revealed that there was no significant associated established either positive or negative in both tests (P>0.05).

Association between hearing loss and birth asphyxia



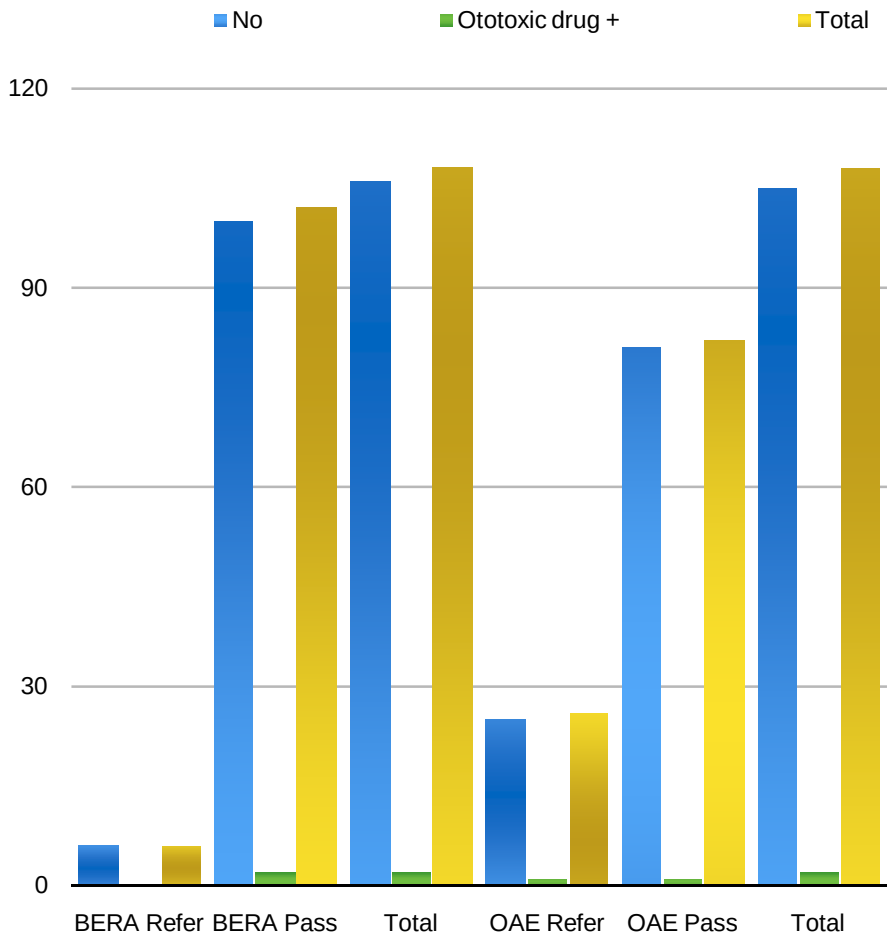
birth asphyxia	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	135	141	χ^2=.000	26	115	141	χ^2=0.000
YES	0	3	3	df=1	0	3	3	df=1
Total	6	138	144	P=1.00	26	118	144	P=1.00

Table -7 shows the association between positive and negative with birth asphyxia of BERA 90 and OAE. The results revealed that there was no significant associated established either positive or negative in both tests (P>0.05).

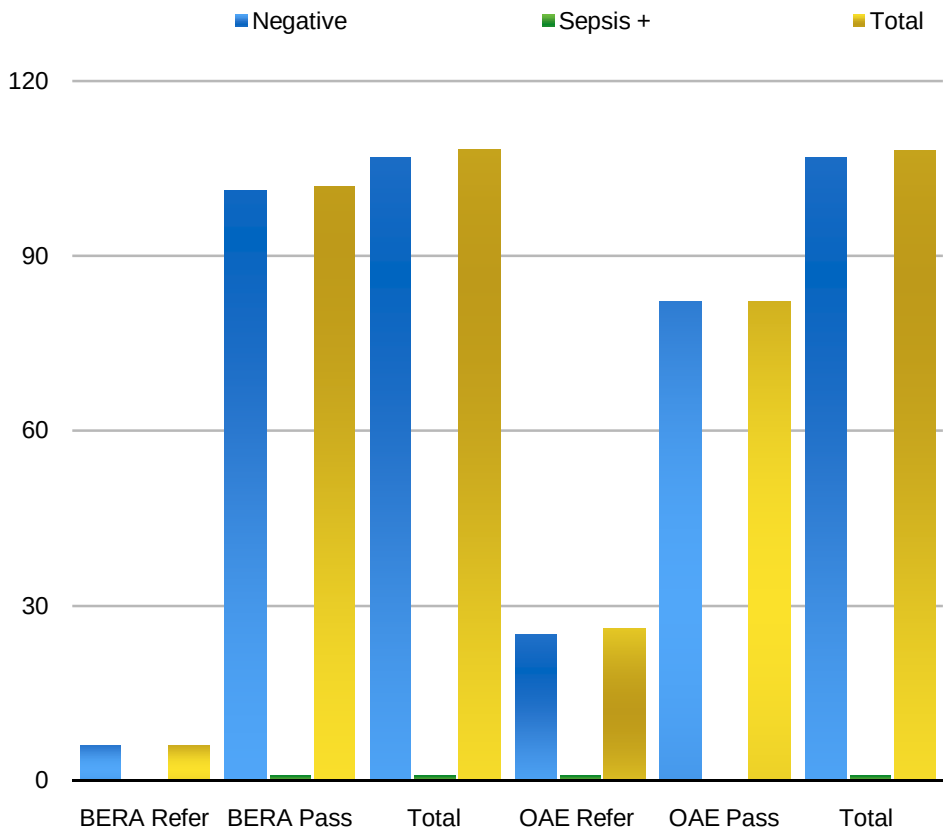
Ototoxic drug	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	136	142	χ^2=.000	25	117	142	χ^2=0.000
YES	0	2	2	df=1	1	1	2	df=1
Total	6	138	144	P=1.00	26	118	144	P=1.00

Table -8 shows the association between Ototoxic drugs and hearing loss with BERA 90 and OAE. The results revealed that there was no significant association, established either positive or negative in both tests (P>0.05).

Association between hearing loss and Ototoxic drug



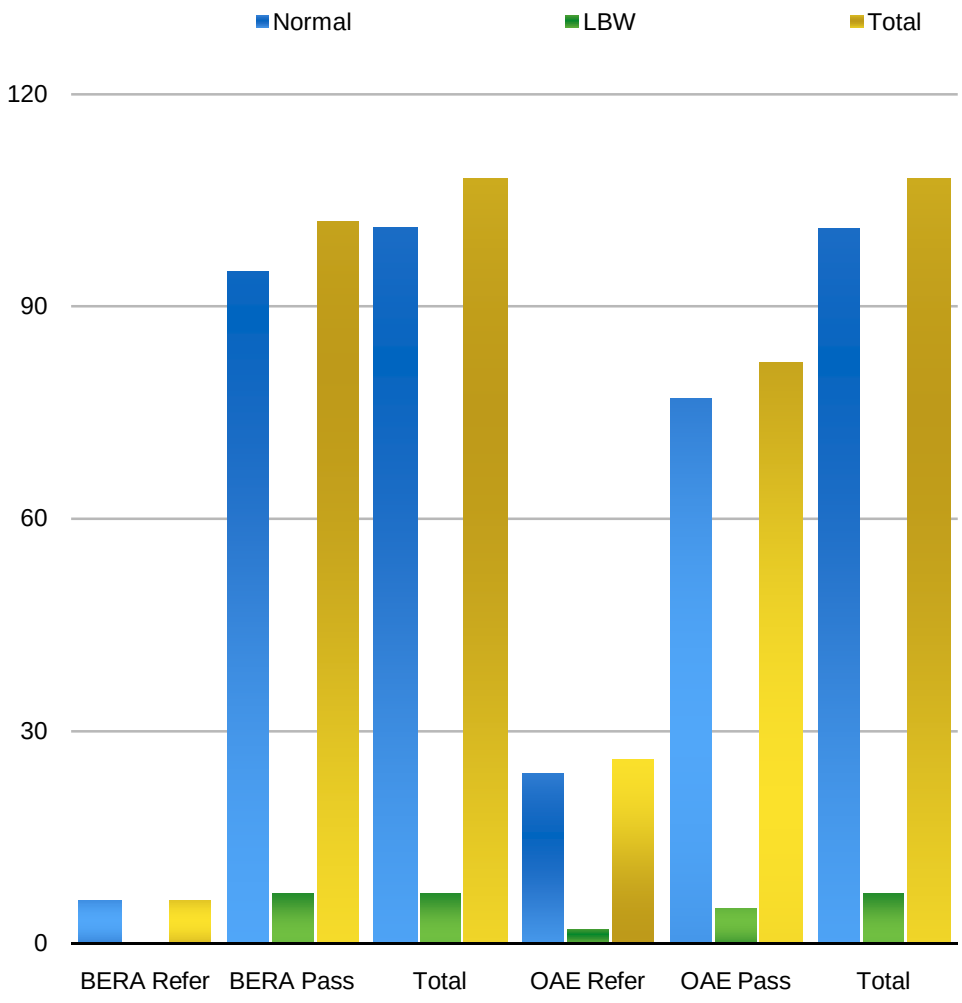
Association between positive and negative of Sepsis



Sepsis	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	137	143	χ^2=.000	25	118	143	χ^2=0.000
YES	0	1	1	df=1	1	0	1	df=1
Total	6	138	144	P=1.00	26	118	144	P=1.00

Table -9 shows the association between positive and negative with Sepsis of BERA 90 and OAE. The results revealed that there was no **significant associated** established either positive or negative in both tests (P>0.05).

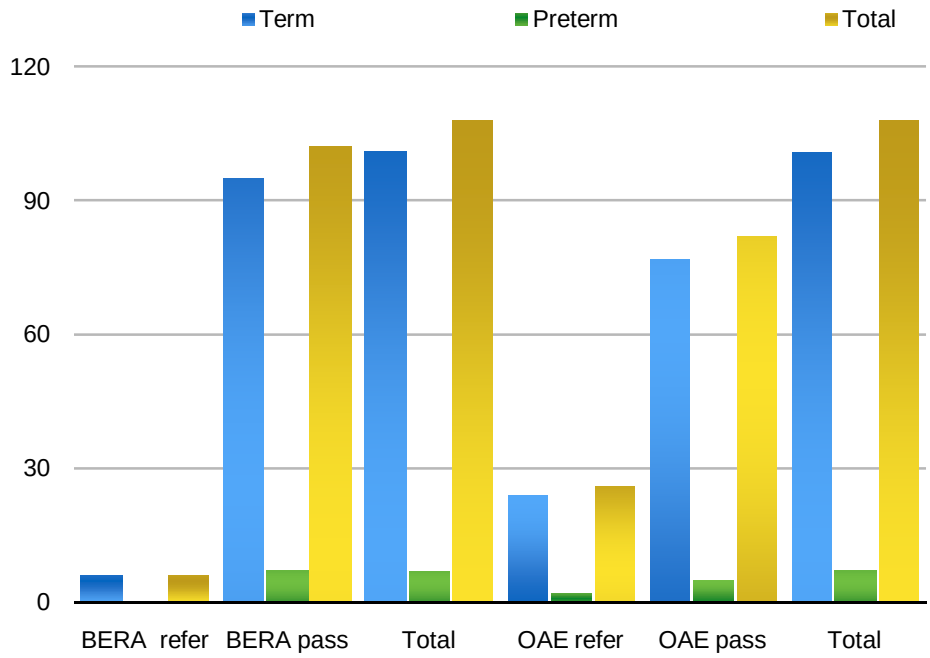
Association between hearing loss and birth weight:



Birth weight	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
Normal	6	131	137	χ^2=.000	24	113	137	χ^2=0.000
Abnormal	0	7	7	df=1	2	5	7	df=1
Total	6	138	144	P=1.00	26	118	108	P=1.00

Table -10 shows the association between positive and negative with birth weight of BERA 90 and OAE. The results revealed that there was no significant associated established either positive or negative in both tests (P>0.05).

Association between maturity and hearing loss



Term	BERA 90 db				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
Full term	6	131	137	χ^2=.000	24	113	137	χ^2=0.000
Pre term	0	7	7	df=1	2	5	7	df=1
Total	6	138	144	P=1.00	26	82	144	P=1.00

Table -11 shows the association between positive and negative with term of BERA 90 and OAE. The results revealed that there was no significant associated established either positive or negative in both tests (P>0.05).

RESULTS

Among the hundred and fifty babies screened, 26 failed OAE while 6 failed BERA.

Referral rate was 18.1% with OAE and 4.2% with BERA

All 6 babies failed with 40db and 90 db screening.

They failed in behaviour response audiometry done subsequently.

BERA hence is considered gold standard in hearing screening.

Mean duration of NICU stay had a positive correlation with BERA positivity.

Average duration of BERA positive cases (15.3 days) was significantly higher than BERA negative cases (11.3)

Babies with higher duration of NICU stay had greater probability of hearing loss.

Age and Sex had no significant correlation with hearing loss.

One case with sepsis had hearing loss identified with OAE but it passed BERA in both ears.

One case with history of ototoxic drug administration had the result REFER with OAE. But it passed BERA in both ears.

Sensitivity of OAE as 16.7 % and the specificity was 81.9 %.

Positive likelihood ratio with OAE was .923

Negative likelihood ratio with OAE was 1.02

Among 6 cases with profound hearing loss one had neonatal jaundice. Two cases with hearing loss identified by OAE was preterm.

DISCUSSION

OAE had a higher referral rate compared to BERA and since overall prevalence of deafness was 1.4 %, false positive results are significantly more with OAE. Since referral leads to unwanted parental anxiety and and additional visits to higher institution for confirmatory audiometric investigation, BERA is a better tool for screening.

All 6 babies identified with BERA failed with behaviour response audiometry too. But BERA was significantly difficult to perform and more expensive.

Among 6 cases with profound hearing loss, one had neonatal jaundice.

No significant correlation exists between hearing loss and the following factors -age, sex and maturity.

Significant correlation exists between hearing loss and mean duration of NICU stay.

SUMMARY

On summarising, the diagnostic ability of BERA is better than OAE .

OAE has a higher false positive rate hence its use as a screening tool in NICU population is limited.

BERA done at 40 and 90 dB have identical results hence making it gold standard in hearing screening.

CONCLUSION

1. BERA is the gold standard in newborn hearing program
2. OAE has higher referral rate and lower specificity compared to BERA.
3. Cases with Neonatal jaundice, Birth Asphyxia, ototoxic drugs and sepsis have developed hearing loss.
4. No significant association between Sex and Gestational age with hearing loss.

LIMITATIONS

1. Limitations inherent to cross-sectional study exist in this study.
2. Hearing screening needs proper follow-up and repeated testing at 3 month and 6 month as BERA findings have been proven to be reversible in neonatal jaundice.
3. Since prevalence of deafness is 1.6 %, identification of risk factors for deafness requires a larger study with wider set of inclusion criteria.

FUTURE RECOMMENDATIONS

1. Data regarding Universal hearing screening and prevalence of deafness among healthy newborn is lacking in South Indian population.
2. Cohort study with complete follow up till audiological recovery could be done with emphasis on the importance of early screening. This can be compared with cohort of unscreened babies with late audiological intervention and their handicaps.
3. Larger sample size can be studied to analyse all the risk factors for hearing loss. Previous data has shown significant association between low birth weight birth asphyxia and neonatal jaundice.
4. Extreme premature neonates should be studied separately owing to neurological immaturity of evoked responses.
5. Newer modalities like Cortical evoked response audiometry (CE-RA) could be explored. CERA is much easier to perform and frequently used in adult hearing. Its relevance in newborn screening needs to be assessed.
6. Importance of Behaviour response audiometry and possibility of training paediatricians and NICU nurses in hearing assessment could be studied. This could be compared with regular program and feasibility trial could be done. This is essential in SNCUs and primary care set-up where proper audiological facility is a luxury.

7. Multiple protocols could be studied in Randomised controlled study- comparing 2 stage (OAE and BERA) and single stage screening. ABR and confirmatory BERA could be done and studied at various levels.

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ABBREVIATIONS

BERA	-	Brainstem Evoked Response Audiometry
OAE	-	Oto-acoustic Emission
ASSR	-	Auditory steady state response
RBSK	-	Rashtriya Bal Swasthya Karyakram
BOA	-	Behavioural Observation Audiometry

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. R.Karthik
Postgraduate M.D.(Paediatrics)
Madras Medical College
Chennai – 600 003.

Dear Dr.R.Karthik,

The Institutional Ethics Committee has considered your request and approved your study titled **"Diagnostic ability of Otoacoustic emission and automated brain stem response audiometry in high risk new born" No.40012015.**

The following members of Ethics Committee were present in the meeting held on 20.01.2015 conducted at Madras Medical College, Chennai-3.

1. Dr.C.Rajendran, M.D.,	: Chairperson
2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Md.Ali, M.D., D.M., Prof. & HOD of Madl.G.E., MMC	: Member
7. Prof.Uma Shanthi, Director i/c, Inst.of O&G, Chennai-3	: Member
8. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
9. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
10. Prof.S.G.Sivachidambaram, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
11. Thiru S.Rameshkumar, Administrative Officer	: Lay Person
12. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
13. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/ informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee
MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

ANNEXURE I - PROFORMA

Name :

Age :

IP No :

Study No :

Address/Contact details :

History

Antenatal :

Fever	☐
Medications	☐
Jaundice	☐
Antibiotic	☐

Natal :

Birth weight	☐
Term/Preterm	☐
Birth Asphyxia	☐
Mode of delivery	☐

Post natal :

NICU admission	☐
Seizure	☐
IV Antibiotics	☐
Jaundice	☐
Lethargy	☐

Clinical Exam :

Sensorium

Jaundice

Pallor

Head to foot :

Microcephaly

Sutures and Fontanelles

Facial dysmorphism

Cataract

Ear anomalies :

CNS :

Tone

Palpebral

Moro

Course during Hospital stay

NICU :

Duration	Mechanical ventilation	Antibiotics

Jaundice :

Peak serum bilirubin	Phototherapy	Exchange transfusion

	RE	LE
TEOAE		
BERA 90 dB		
40 dB		

INFORMED CONSENT FORM

Study place: INSTITUTE OF CHILD HEALTH AND HOSPITAL FOR CHILDREN, INSTITUTE OF OBSTETRICS AND GYNAECOLOGY

Title of the study: **DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARING SCREENING OF HIGH RISK NEWBORN**

Name of the investigator : R.Karthik

Name of the Participant: Age: Sex:

Hospital number: Study no:

1. I have read and understood this consent form and the information provided to me regarding the participation in the study.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have informed the investigator of all the treatments I am taking or have taken in the past

including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.*

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer

unusual symptoms. *

8. I have not participated in any research study in the past.

10. I am aware of the fact that I can opt out of the study at any time without having to give any reason

and this will not affect my future treatment in this hospital. *

11. I am also aware that the investigator may terminate my participation in the study at any time, for

any reason, without my consent. *

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understand that my identity will be kept confidential if my data are publicly presented

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing

this consent form I attest that the information given in this document has been clearly explained to me

and understood by me, I will be given a copy of this consent document. For adult participants:

Name and signature / thumb impression of the participant /parents/guardian

Name _____ Signature_____
Date_____

Name and Signature of impartial witness:

Name _____ Signature_____
Date_____

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____
Date_____

INFORMATION SHEET

Place of study: INSTITUTE OF CHILD HEALTH AND HOSPITAL FOR CHILDREN, INSTITUTE OF OBSTETRICS AND GYNAECOLOGY.

Name of Investigator : R.Karthik

Name of Participant age: sex:

Hospital No: Study No:

Study title : **DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARINGSCREENING OF HIGH RISK NEWBORN·**

We are conducting a study on "**DIAGNOSTIC ABILITY OF OTO-ACOUSTIC EMISSION AND BRAIN STEM EVOKED RESPONSE AUDIOMETRY IN HEARINGSCREENING OF HIGH RISK NEWBORN"**

We request you to participate in the study

- The purpose of this study is to compare Oto-acoustic emission and Brainstem evoked response audiometry in hearing screening in high risk newborn
- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

• Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

• The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant/parent/guardian

Date:

சுய ஒப்புதல் படிவம்

ஆய்வு தலைப்பு : ஒட்டோ அக்வஸ்டிக் எமிஷன் (OAE) மற்றும் பிரைன் ஸ்டெம் எவொக் ரெஸ்பான்ஸ் ஆடியோமெட்ரி (BERA) கொண்டு தீவிர சிகிச்சை பெற்ற பச்சிளங்குழந்தைகளின் காது கேட்கும் திறன் கண்டறிவது பற்றி ஒரு ஆய்வு.

இடம் : அரசு குழந்தை நல மருத்துவமனை, எழும்பூர், சென்னை-8.

குழந்தையின் பெயா :
த/பெயர் : தேதி :
வயது : உள்/வெளி நோயாளி எண் :
பாலினம் : ஆராய்ச்சி சேர்க்கை எண் :

..... என்பவராகிய நான் இந்த ஆய்வின் விவரங்களை படித்து தெரிந்து கொண்டேன் (அல்லது) எனக்கு படித்து சந்தேகங்கள். அதன் நோக்கங்களும் முறையாக அறிந்து கொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுயநினைவுடன் பங்குகொள்ள சம்மதிக்கிறேன்.

1. இந்த ஒப்புதல் படிவத்தை நான் படித்து புரிந்து கொண்டேன்.
2. இச்சுய ஒப்புதல் படிவத்தை பற்றி எனக்கு விளக்கப்பட்டது.
3. இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது.
4. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினை பற்றி அறிந்து கொண்டேன்.
5. தற்போது என் குழந்தை எடுத்துக் கொண்டிருக்கும் (அல்லது) முன்பு எடுத்துக் கொண்ட மருத்துவ விவரங்களை ஆய்வாளர்களுக்கு தெரிவித்துள்ளேன்.
6. இந்த ஆய்வின் என் குழந்தையின் பங்களிப்பினால் குழந்தைக்கு எந்த பின்விளைவுகளும் ஏற்படாது. ஏனெனில் இவை உடம்பில் துறையில்லா (Non-Invasive) முறைபடி செய்யப்படுபவை.
7. இந்த ஆராய்ச்சியில் இருந்து நான் எந்நேரமும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.
8. ஆய்வாளர் இந்த ஆய்வில் என் குழந்தையின் பங்களிப்பை எந்த நேரத்திலும் எந்த காரணத்திற்காகவும், எந்தவித ஒப்புதல் இல்லாமலும் நிறுத்திக் கொள்ளலாம் எனவும் தெரிவித்து கொண்டேன்.

9. இந்த ஆய்வில் கலந்து கொள்வதன் மூலம் என் குழந்தையிடம் பெறப்படும் ஆய்வாளர் இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

10. இந்த ஆய்வின் முடிவுகளை வெளியிடும் போது என் குழந்தையின் பெயரோ, அடையாளமோ வெளியிடப்படாது என அறிந்து கொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல் தாளைப் பெற்றுக் கொண்டேன்.

11. எனது எல்லா கேள்விகளுக்கும் திருப்தியாக பதிலளிக்கப்பட்டது.

12. இந்த ஆராய்ச்சியில் பங்களிக்க வேண்டுமென முடிவு செய்துள்ளேன்.

இந்த ஆய்வில் பங்கேற்கும் பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால். உடனே ஆய்வாளரை தொடர்பு கொள்ள வேண்டும் என அறிந்து கொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்று தெரிந்து கொண்டேன்.

பங்கேற்பாளர்

பங்கேற்பாளருடைய பெயர் மற்றும் கையொப்பம் / கைரேகை (அல்லது சட்ட ரீதியான பிரதிநிதி - பங்கேற்பாளர் செயல்திறமையற்றவராக இருந்தால் / 17 வயதிற்கு கீழ் உள்ளவர்களுக்கு - பெற்றோர் / பாதுகாவலர்)

....

பெயர் கையொப்பம் / கைரேகை தேதி

நடுநிலையிலுள்ள சாட்சியாளரின் பெயர் மற்றும் கையொப்பம் (படிப்பறிவு இல்லாத மக்களுக்கு)

....

பெயர் கையொப்பம் / கைரேகை தேதி

நடுநிலையிலுள்ள சாட்சியாளரின் முகவரி மற்றும் தொலைபேசி எண்

....

ஆராய்ச்சியாளரின் பெயர் கையொப்பம் தேதி

தகவல் படிவம்

ஆய்வு தலைப்பு : ஒட்டோ அக்வஸ்டிக் எமிஷன் (OAE) மற்றும் பிரைன் ஸ்டெம் எவொக் ரெஸ்பான்ஸ் ஆடியோமெட்ரி (BERA) கொண்டு தீவிர சிகிச்சை பெற்ற பச்சிளங்குழந்தைகளின் காது கேட்கும் திறன் கண்டறிவது பற்றி ஒரு ஆய்வு.

இடம் : அரசு குழந்தை நல மருத்துவமனை, எழும்பூர், சென்னை-8.

ஆய்வாளரின் பெயர் : கார்த்திக்.இரா
குழந்தையின் பெயர் :
த/பெயர் : தேதி :
வயது : உள்/வெளி நோயாளி எண் :
பாலினம் : ஆராய்ச்சி சேர்க்கை எண் :

1. தீவிர சிகிச்சை பெற்ற பச்சிளங்குழந்தைகளின் காது கேட்கும் திறன் கண்டறிவதே இந்த ஆராய்ச்சியின் நோக்கம்.
2. இவை உடம்பில் துறையில்லா முறைகள் மூலம் (Non-Invasive) செய்யப்படுகிறது.
3. இந்த ஆய்வின் மூலம் கண்டறியப்படும் முடிவுகள் உங்கள் குழந்தையின் சிகிச்சைக்கு மிகவும் உதவியாக இருக்கும்
4. இந்த ஆய்வின் மூலம் கண்டறியப்படும் முடிவுகள் உங்கள் குழந்தையின் சிகிச்சைக்கு மிகவும் உதவியாக இருக்கும்.
5. இந்த ஆய்வில் கலந்து கொள்வதன் மூலம் என் குழந்தையிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸடிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.
6. உங்கள் குழந்தையை பற்றிய விபரங்கள் யாருக்கும் தெரிவிக்காமல் பாதுகாக்கப்படும்.
7. இந்த ஆய்வில் பங்குபெறுவது உங்கள் தனிப்பட்ட விருப்பம் ஆகும். நீங்கள் இந்த ஆய்விலிருந்து எப்பொழுது வேண்டுமானாலும் விலகிக் கொள்ளலாம். அவ்வாறு விலகுவதால் குழந்தையின் சிகிச்சையில் எவ்வித பாதிப்பும் ஏற்படாது.

8. ஆய்வாளர் இந்த ஆய்வில் என் குழந்தையின் பங்களிப்பை எந்த நேரத்திலும் எந்த காரணத்திற்காகவும், எந்தவித ஒப்புதல் இல்லாமலும் நிறுத்திக் கொள்ளலாம் எனவும் தெரிந்து கொண்டேன்.

9. ஆய்வில் பங்கு கொள்ளும் போது ஏதேனும் சந்தேகம் ஏற்பட்டால் ஆய்வாளரை தொடர்பு கொள்ளலாம்.

இச்சுய தகவல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கிறேன். இச்சுய படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்று தெரிந்து கொண்டேன்.

பங்கேற்பாளர்

பங்கேற்பாளருடைய பெயர் மற்றும் கையொப்பம் / கைரேகை (அல்லது சட்ட ரீதியான பிரதிநிதி - பங்கேற்பாளர் செயல்திறமையற்றவராக இருந்தால் / 17 வயதிற்கு கீழ் உள்ளவர்களுக்கு - பெற்றோர் / பாதுகாவலர்)

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பெயர் கையொப்பம் / கைரேகை தேதி

நடுநிலையிலுள்ள சாட்சியாளரின் பெயர் மற்றும் கையொப்பம் (படிப்பறிவு இல்லாத மக்களுக்கு)

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பெயர் கையொப்பம் / கைரேகை தேதி

நடுநிலையிலுள்ள சாட்சியாளரின் முகவரி மற்றும் தொலைபேசி எண்

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ஆராய்ச்சியாளரின் பெயர் கையொப்பம் தேதி

MASTER CHART

Name	Days	Sex	NICU	NNH	Birth Asphyxia	Family history of hearing loss	Ototoxic drugs	Ear Anomalies	Sepsis	Birth weight	Preterm	OAE left	OAE right	BERA left 90 db	BERA right 90 db	BERA left 40db	BERA right 40 db
B/o Bhuvaneshwari	15	1	9	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/o Saraladevi	23	1	18	1	1	1	1	1	1	1	1	**2**	1	1	1	1	1
B/O Dhanalakshmi	22	**2**	20	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Saisaran	21	**2**	15	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/O Jayanthi	18	**2**	12	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/O Muthulakshmi	24	1	14	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/O Premila twin 1	21	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/O Premila twin 2	28	**2**	14	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Thasleem	16	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Ammu	10	**2**	9	1	1	1	1	1	1	1	1	**2**	1	**2**	**2**	**2**	**2**
Priya	15	**2**	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Nazeera	14	1	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Lakshmi	10	1	8	1	1	1	1	1	1	1	1	1	**2**	**2**	**2**	**2**	**2**
B/o Tamilselvi	10	1	8	1	1	1	1	1	1	1	1	**2**	1	1	1	1	1
B/o Latha	7	**2**	6	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Nathiya	16	**2**	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Kalaiselvi	15	**2**	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Shobana	15	1	11	1	1	1	1	1	1	1	1	1	1	**2**	**2**	**2**	**2**
B/o Muthukamatchi	15	**2**	10	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Gomathi	27	**2**	21	1	1	1	1	1	1	1	1	**2**	**2**	**2**	**2**	**2**	**2**
B/o Karthika	30	**2**	21	1	1	1	1	1	1	1	1	**2**	**2**	**2**	**2**	**2**	**2**
B/o Tharamary	12	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Selvi	15	**2**	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Kalaiarasi Twin 1	23	1	14	1	1	1	1	1	1	1	1	1	1	1	1	1	1

B/o Kalaiarasi Twin 2	23	1	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Saruna	28	1	19	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Kalavathy	9	**2**	7	**2**	1	1	1	1	1	**2**	**2**	1	1	1	1	1	1
B/o Geetha	10	**2**	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Parameshwari	30	1	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Renuka	9	1	7	**2**	1	1	1	1	1	**2**	**2**	1	1	1	1	1	1
B/o Uma Maheshwari	14	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Parimala	8	**2**	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Manju	12	1	11	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Sithiraikani	7	**2**	6	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/o Patchaiyammal	10	1	8	1	1	1	1	1	1	1		1	1	1	1	1	1
B/o Fathima	14	**2**	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Muniyammal	13	1	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Sharmila	8	1	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o devi	7	**2**	5	1	1	1	1	1	1	1	1	**2**	1	1	1	1	1
B/o Athilakshmi twinI	20	1	18	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Athilakshmi twin2	20	**2**	17	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/O Devi II	7	1	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/O Seethalakshmi	11	1	10	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Amudha	12	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Pencillama twin1	12	1	10	1	1	1	1	1	1	1	1	**2**	1	1	1	1	1
B/o Pencillama twin2	12	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Geetha	13	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Saranya	24	**2**	16	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/o Lakshmi	13	1	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Amudha II	10	1	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Ananthi	10	**2**	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1

B/o Zahidha twin 1	22	**2**	18	1	1	1	1	1	1	1	1	1	**2**	1	1	1	1
B/o Zahidha twin 2	22	**2**	20	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Baby	9	**2**	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Radhika	14	1	11	1	1	1	1	1	1	1	1	**2**	1	1	1	1	1
B/o Arasu	21	**2**	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Renuka II	22	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Parameshwari	23	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o selvamani kumari	24	1	14	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Nathiya	18	1	13	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Karthiga	17	1	14	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Shobana Rajalakshmi	15	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Yalini	30	**2**	22	**2**	1	1	1	1	1	1	1	1	**2**	**2**	**2**	**2**	1
B/o Gomathy II	30	1	18	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Muthu	28	1	12	**2**	1	1	**2**	1	1	1	1	1	**2**	1	1	1	1
B/o draupathy	21	1	14	1	1	1	1	1	**2**	1	1	1	**2**	1	1	1	1
B/o Rajathi	20	**2**	21	**2**	1	1	1	1	1	1	**2**	1	1	1	1	1	1
B/o Vanitha	29	1	11	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Sasirekha	21	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Devi twin I	22	**2**	20	1	1	1	1	1	1	**2**	**2**	1	1	1	1	1	1
B/o Devi twin II	21	1	21	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Amudhamalar	18	1	17	1	1	1	1	1	1	**2**	1	**2**	**2**	1	1	**2**	**2**
B/o Sheik Afree	21	**2**	13	**2**	1	1	1	1	1	**2**	**2**	1	**2**	1	1	1	1
B/o Sailakshmi	19	1	18	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Adhisakthi	19	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Nahajabeen	21	1	18	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Naganna	20	1	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Sharnila	18	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1

B/o Gayathri	17	**2**	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Saranya	13	1	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Aruna	8	1	5	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Rekha	10	**2**	8	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Helen jaya	11	1	7	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Parimala 2 twin 1	21	1	12	**2**	1	1	1	1	1	**2**	**2**	1	1	1	1	1	1
B/o Parvathy	22	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Ramya	28	1	13	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o mohanapriya	14	**2**	11	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Shakila	11	1	8	1	**2**	1	1	1	1	1	1	1	1	1	1	1	1
B/o Parveen	12	1	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Jamunarani	16	**2**	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Sarala	14	**2**	6	1	1	1	1	1	1	**2**	1	1	1	1	1	1	1
B/o Jansirani	12	1	8	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Sandhya triplet 1	13	1	7	**2**	1	1	1	1	1	1	**2**	1	1	1	1	1	1
B/o Sandhya triplet 2	13	1	7	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Sandhya triplet 3	13	1	7	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
Jabul nisha	16	**2**	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Jayashri	21	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Anandhi	20	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Athilakshmi 2	11	**2**	10	1	**2**	1	1	1	1	1	1	1	1	1	1	1	1
B/o Uma	23	1	8	1	1	1	1	1	1	1	1	**2**	**2**	1	1	1	1
B/o Saruna	19	1	9	1	**2**	1	1	1	1	1	1	1	1	1	1	1	1
B/o Kalaiarasi 2	18	1	7	1	1	1	**2**	1	1	1	1	1	1	1	1	1	1
B/o Thara	9	**2**	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Selvi 2	12	**2**	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o niranjana	9	**2**	7	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1

B/O veena	27	1	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o nandini	20	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o sowbagya	18	**2**	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o ashwini	13	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o malarvili	14	1	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o suganthi	30	**2**	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o jaya	23	1	13	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o jothi	22	**2**	20	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o chamundeeswari	9	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o harini	18	**2**	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o dharani	24	**2**	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o hemavathi	12	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o padmini	22	1	13	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o kamala	26	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o rajeswari	8	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o divyalakshmi	15	1	9	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o shandhi	16	**2**	9	**2**	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o pushpalatha	12	**2**	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o kalaivani	14	**2**	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/O Seetha	14	1	12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o vimala	21	1	14	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Geetha II	25	1	18	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o valarmathi	11	**2**	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Kavitha	14	1	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Maria	15	1	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o banumathi	23	1	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Jansi	11	1	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1

B/o punitha mary	13	**2**	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o lavanya	13	**2**	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o charumathy	8	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o Selvamani	9	**2**	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o thilagavathy	9	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o malli	12	**2**	11	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o gunamathi	21	1	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o raji	21	1	15	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o reena	24	**2**	17	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o vanmathi	30	**2**	19	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o ramani	11	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
B/o leelavathy	13	1	8	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

KEY TO MASTER CHART

A.SEX

1 - Male

2 - Female

B.NNH

1 - Neonatal hyperbilirubinemia absent

2 - Neonatal hyperbilirubinemia present

C.Birth Asphyxia

1 - Birth Asphyxia absent

2 - Birth Asphyxia present

D.Family history of hearing loss

1 - Family history of hearing loss absent

2 - Family history of hearing loss present

E.Ototoxic drugs

1 - Ototoxic drugs not given

2 - Ototoxic drugs given

F.Ear Anomalies

1 - Ear Anomalies absent

2 - Ear Anomaliespresent

G.Sepsis

1 - Sepsis absent

2 - Sepsis present

H.Birth weight

1 - Normal Birth weight

2 - Low or Very Low birth weight

I.Prematurity

1 - Term

2 - Premature

J.OAE left ,OAE right, BERA left 90 db,BERA right 90 db,BERA left 40 db,BERA left 40 db

1 - Pass

2 - Refer